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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/583,013 | 06/15/2006 | Julia Adam-Worrall | 2003.807US | 6111 |

67706 7590 09/08/2008

ORGANON USA, INC.
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| EXAMINER |
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BERNHARDT, EMILY B

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| ART UNIT | PAPER NUMBER |
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1624

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| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

09/08/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jill.corcoran@spcorp.com
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| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/583,013 | Applicant(s) ADAM-WORRALL, JULIA | |
| | Examiner EMILY BERNHARDT | Art Unit 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6 and 8-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,8-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

In view of applicants' response filed on 6/4/08 the following applies.

Claims 1-4,6,8-12 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for unfused piperazines and octahydro pyrido[1,2-a]pyrazine ring system, exemplified in egs 2 and 3, does not reasonably provide enablement for remaining scope of ring systems permitted by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and thus use the invention commensurate in scope with these claims. The claims cover in addition to the fused 6-membered pyrido ring pointed out by applicants rings that can be 4- to 7-membered having in addition to carbon atoms O or S atoms. There is no discussion in the specification that starting material sources needed to prepare such ring systems are readily available. Note the following passage in In re Howarth (previously cited) at p.690: "Applicants' risk in leaving anything out of his application...burden rests upon applicant who chooses to rely upon general knowledge in art to render his disclosure enabling to establish that those of ordinary skill in the art can be expected to possess or know where to obtain this knowledge;" .

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating pain covered by claim 11, does not reasonably provide enablement for scope of uses covered in claim 12. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with

Art Unit: 1624

these claims. The claim has been amended to recite various disorders. The notion that CB1 agonists have such a range of uses including diseases such as Alzheimer's, Huntington's disease, all forms of dementias, sleep disorders such as Intrinsic Sleep Disorders, including Psychophysiological Insomnia, Sleep State Misperception, Idiopathic Insomnia, Narcolepsy, Recurrent Hypersomnia, Idiopathic Hypersomnia, Posttraumatic Hypersomnia, Obstructive Sleep Apnea Syndrome, Central Sleep Apnea Syndrome, Central Alveolar Hypoventilation Syndrome, Periodic Limb Movement Disorder, Restless Legs Syndrome, and Intrinsic Sleep Disorder NOS, Inadequate Sleep Hygiene, Environmental Sleep Disorder, Altitude Insomnia, Adjustment Sleep Disorder, Insufficient Sleep Syndrome, Limit-Setting Sleep Disorder, Sleep-Onset Association Disorder, Food Allergy Insomnia, Nocturnal Eating (Drinking) Syndrome, Hypnotic-Dependent Sleep Disorder, and sleepwalking to name just a few has not been substantiated in the current art. As far as the examiner is aware there are currently no CB1 agonists in clinical trials for any one sleep disorder listed above much less an entire class. The same applies to the remaining scope of disorders being claimed including all cardiovascular, neurodegenerative, and respiratory disorders. Note Hogenauer, a recent article at best shows one CB1 agonist in Phase III clinical trial for the treatment of pain. See discussion on p.1459.

Note also the criteria for enablement as set out in *In re Wands* cited in MPEP

2164.01(a), August 2000 edition which considers factors such as:

- 1) Breadth of the claims- The claims cover a wide range of diseases as discussed above;

Art Unit: 1624

2) Level of skill in this art- the examiner has pointed out above that drugs having the activity relied on herein are not known to have such a spectrum of clinical applications and thus the level of skill is low ;

3) State of the prior art- compounds similar in structure have not been reported to be clinically active for such a range of uses;

4) Working examples- There are no test(s) directed to the many uses pointed out above which are art-recognized for predicting *in vivo* efficacy .

Thus in view of the above the rejection is being applied.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 1624

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Bernhardt/
Primary Examiner, Art Unit 1624